Law Offices
James A. Dunlap Jr. & Associates LLC
310 Windsor Gate Cove NE
Atlanta, Georgia 30342

Phone: (404) 354-2363 **E-mail:**
Fax: (404) 745-0195 **jim@jamesdunlaplaw.com**

June 28, 2013

VIA REGULAR MAIL, FAX, and EMAIL

Melanie M. Hill, Executive Director
Tennessee Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Boulevard
Nashville, TN 37243

Re: **Application for Certificate of Need**
Applicant: Tri-Cities Holdings LLC d/b/a Trex Treatment Center
Application No. CN1303-005

Dear Ms. Hill:

This letter follows up on my letter of June 17, 2013, and my verbal request made during the June 27, 2013 Tennessee Department of Health Services and Development Agency ("HSDA") Certificate of Need hearing ("CON hearing") for the establishment of an Opiate Treatment Program ("OTP") in Johnson City, Tennessee. I understood that the Chairman, at the conclusion of the CON hearing, directed to me to contact HSDA staff to pursue my request for a reasonable modification or accommodation under the Americans with Disabilities Act ("ADA") and the Rehabilitation Act of 1973 ("RA").

As you know, I represent Tri-Cities Holdings LLC d/b/a Trex Treatment Center ("TCH"), the above-captioned applicant. In addition, I also represent eight (8) residents of the Johnson City, Tennessee area who are addicted to opiates and who are recognized as disabled under federal law, including the ADA and the RA. This proposed clinic will allow my Individual Clients--along with hundreds of other similarly disabled area residents which include pregnant women – to have access to doctor-prescribed, life-saving, "standard of care"[1] methadone maintenance treatment

[1] The term "standard of care" treatment is generally recognized as treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Standard of care is also called "best practice," "standard medical care," and "standard therapy. National Cancer Institute at the National Institute of Health (http://www.cancer.gov/dictionary?cdrid=346525).

(MMT) for the first time in the proposed service area. Presently, this standard of care, life-saving treatment is available only in distant out-of-state clinics (primarily in North Carolina) offering standard of care treatment more than 100 miles roundtrip, over potentially dangerous mountain roads in all weather conditions, from many parts of the proposed service area. At present, MMT standard of care treatment is available at approximately 1,300 clinics across the United States and at least twelve other clinics in other parts of Tennessee.

I regret having to make this demand after what was certainly a very pleasant, knowledgeable, and attentive panel at the CON hearing on June 26, 2013. But unfortunately, my clients – and at least 400-500 and as many as 1,500 other opiate-addicted person in the proposed service area -- are literally at risk of dying from lack of reasonable access to doctor-prescribed, standard of care treatment which is nowhere currently available in the proposed service area. My clients have directed me take all steps necessary to persuade HSDA to act on what is clearly a lack of of life-saving MMT treatment for my clients, and others which include pregnant women and their unborn babies, in the proposed service area. This lack of reasonable access to standard of care treatment for opiate addiction presents a clear and present danger to my clients and others, including pregnant women and their unborn babies, which include severe physical injury or death.

We contend, at all times respectfully, that the HSDA panel incorrectly rejected the CON application on the applicable criteria. However, in addition and up-to-this-point, HSDA has not made a reasonable modification of its rules and regulations required under the ADA and RA to allow the CON to be granted. Making a reasonable accommodation and granting the CON will avoid the clear and present danger to my clients--and hundreds of other recovering opiate-addicts, including pregnant women---because standard of care, doctor-prescribed, life-saving treatment is effectively denied them by being a more than 100 miles away roundtrip over potentially dangerous mountain roads in all weather conditions.[2]

---

[2] The negative effects of denying reasonable access to treatment exemplify the concerns driving the Supreme Court's analysis in *Olmstead v. L.C.* that unnecessary segregation is a violation of the ADA. *Olmstead v. L.C.*, 527 U.S. at 600-01; *Long v. Benson*, No. 08cv26, 2008 WL 4571903 *2 (N.D. Fla. Oct. 14, 2008)(citations). See *Payne v. Arizona*, No. CV 09-01195-PHX-NVW, April 5, 2012 (D. Ariz., 2012)("[A] Plaintiff may have a valid claim under the ADA where he can show that Defendant "discriminated against [him] because of his [disability] … by denying him immediate

I would respectfully submit that HSDA could easily modify one or all of the criteria related to need, economic feasibility, and orderly development (and for that matter, any and all other rules, if any, presently stopping the CON from being issued) and allow the CON application to be approved.[3] Specifically, despite the panel finding insufficient "need," TCH stands ready proceed to open its clinic and serve the Individual Clients, in addition to any whatever additional patients that may decide to patronize the proposed clinic at TCH's own risk.

I respectfully request--but do not demand---that HSDA do this by July 5, 2013, so as to enable my clients to avoid additional damage by reason of any delay its process of TCH establishing its OTP clinic and to allow my clients time to consider and pursue other procedural steps or remedies. In the alternative, that HSDA decide that it will refuse to provide any modification to allow the CON to be approved, I ask that you notify me promptly so that I may take next steps through an administrative appeal, or state or federal court action, to protect my clients' interests.

BACKGROUND

This request for an accommodation or modification is brought pursuant to the Americans with Disabilities Act, 42 U.S.C. § 12101 et seq., and Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794. My clients seek a reasonable modification or accommodation from HSDA under the Rehabilitation Act and the ADA to allow HDSA's to approve TCH's application for a Certificate of Need.

Chemical dependency is a life threatening disease, which, if left untreated, poses a serious risk to the health, safety and well-being of the victim, his/her family and the community in which he/she resides. TCH targets clients with a primary dependence on opiates. TCH will use the latest medical technologies, including methadone maintenance treatment, to address the physical symptoms of the addiction in combination with the psychotherapeutic interventions proven most effective to address the emotional, cognitive and behavioral symptoms of its patients. TCH's programs will be "supervised rehabilitation programs" for persons with disabilities as

---

access to prescribed medications[.]" quoting *McNally v. Prison Health Servs*., 46 F. Supp. 2d. 49, 58-59 (D. Me. 1999)).

[3] See Tenn. Code § 68-11-1609 et seq. ("(b) No certificate of need shall be granted unless the action proposed in the application is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of adequate and effective health care facilities or services. In making such determinations, the agency shall use as guidelines the goals, objectives, criteria and standards in the state health plan.).

described under federal law which, importantly, would introduce standard of care MMT into the proposed service area for the first time.

Numerous studies have found that addiction to heroin and other opiates is a chronic medical illness that produces significant and lasting changes in brain chemistry and function. Numerous studies have also found that this medical illness can be effectively treated in a methadone treatment program. For example, in 1997, an expert panel convened at a National Institutes of Health (NIH) Consensus Development Conference on Effective Medical Treatment of Heroin Addiction concluded that opiate addiction is a medical disorder that can be effectively treated in employing standard of care methadone maintenance treatment ("MMT"). This treatment is nowhere available in the proposed service area.

The Rehabilitation Act

The Rehabilitation Act, 29 U.S.C. § 701 et seq., applies to federal government agencies as well as organizations that receive federal funds. Much of the Rehabilitation Act focuses on employment, but section 504 broadly covers other types of programs and activities as well. Section 504(a) provides that "[n]o otherwise qualified individual with a disability in the United States ... shall, solely by reason of her or his disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance ...."

In implementing the Rehabilitation Act, the Department of Health and Human Services ("HHS") promulgated several regulations that specifically require reasonable accommodations. The most pertinent of these regulations requires recipients of federal funds to "make reasonable accommodation to the known physical or mental limitations of an otherwise qualified handicapped applicant or employee unless the recipient can demonstrate that the accommodation would impose an undue hardship on the operation of its program." The Supreme Court has located a duty to accommodate in the statute generally.

Title II of the Americans with Disabilities Act

The ADA was built on the Rehabilitation Act, but extends its reach substantially. Invoking "the sweep of congressional authority, including the power to enforce the fourteenth amendment and to regulate commerce," the ADA was designed "to provide a clear and comprehensive national mandate for the elimination of discrimination against individuals with disabilities." It forbids discrimination against persons with disabilities in three major areas of public life: (1) employment, which is covered by Title I of the statute; (2) public services, programs and activities, which are

the subjects of Title II ; and (3) public and private lodging, which is covered by Title III.

Title II is commonly referred to as the public services portion of the ADA. Title II provides that "no qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity." Section 12131(2) goes on to define "qualified individual with a disability" as an individual with a disability who, with or without reasonable modifications to rules, policies, or practices, the removal of architectural, communication, or transportation barriers, or the provision of auxiliary aids and services, meets the essential eligibility requirements for the receipt of services or the participation in programs or activities provided by a public entity. State agencies are subject to the requirements of Title II.

The Attorney General of the United States, at the instruction of Congress, has issued an implementing regulation that outlines the duty of a public entity to accommodate reasonably the needs of the disabled. The Title II regulation reads:

> A public entity shall make reasonable modifications in policies, practices, or procedures when the modifications are necessary to avoid discrimination on the basis of disability, unless the public entity can demonstrate that making the modifications would fundamentally alter the nature of the service, program, or activity.

Accordingly, federal courts provide that a Title II cause of action under the ADA "may be established by evidence that (1) the defendant intentionally acted on the basis of the disability, (2) the defendant refused to provide a reasonable modification, or (3) the Defendants' rule disproportionally impacts disabled people."

STATEMENT OF FACTS

My Individual Clients are addicted to opiates. This is an impairment that substantially limits a major life activity. My Individual Clients are not engaging in current illegal use of drugs. My Individual Clients are presently participating in a supervised rehabilitation program as defined under the ADA. My Individual Clients are disabled as defined under both the Rehabilitation Act and the ADA.[4] Federal

[4] Section 12102 of the ADA defines disability as follows:

(2) Disability. The term "disability" means, with respect to an individual-

(A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual;

(B) a record of such an impairment; or

(C) being regarded as having such an impairment.

courts uniformly hold that recovery from addiction using methadone treatment is a process that may take weeks, months, or years, and after entering treatment many patients continue to be substantially impaired in their ability to raise families for some time. *MX Group, Inc. v. City of Covington*, 106 F.Supp.2d 914 (E.D. Ky. 2000), *aff'd* 293 F.3d 326 (6th Cir. 2002).[5] Furthermore, federal decisions hold that TCH has associational standing under federal court decisions to assert claim of opiate-addicted persons who would be its patients in the proposed service area.[6]

At the CON hearing, TCH presented the extremely grim statistics from the State of Tennessee Health Plan 2012:

- Tennessee has one of the highest rates of prescription drug abuse in the nation
- Drug overdose deaths in 2010 represents an increase of 250% over the 10 year time period.
- 51 pills of hydrocodone for EVERY Tennessean above the age of 12
- 21 pills of oxycodone for EVERY Tennessean above the age of 12
- Per-capita oxycodone sales increased five- or six-fold in most of Tennessee during the decade.
- Opioid abuse in Tennessee is greater than abuse of marijuana or crack/cocaine
- Prescription drug abuse hits every profession and every socioeconomic level.
- Percentage Tennessee children entering custody with related substance abuse problem from 19% to 33%.

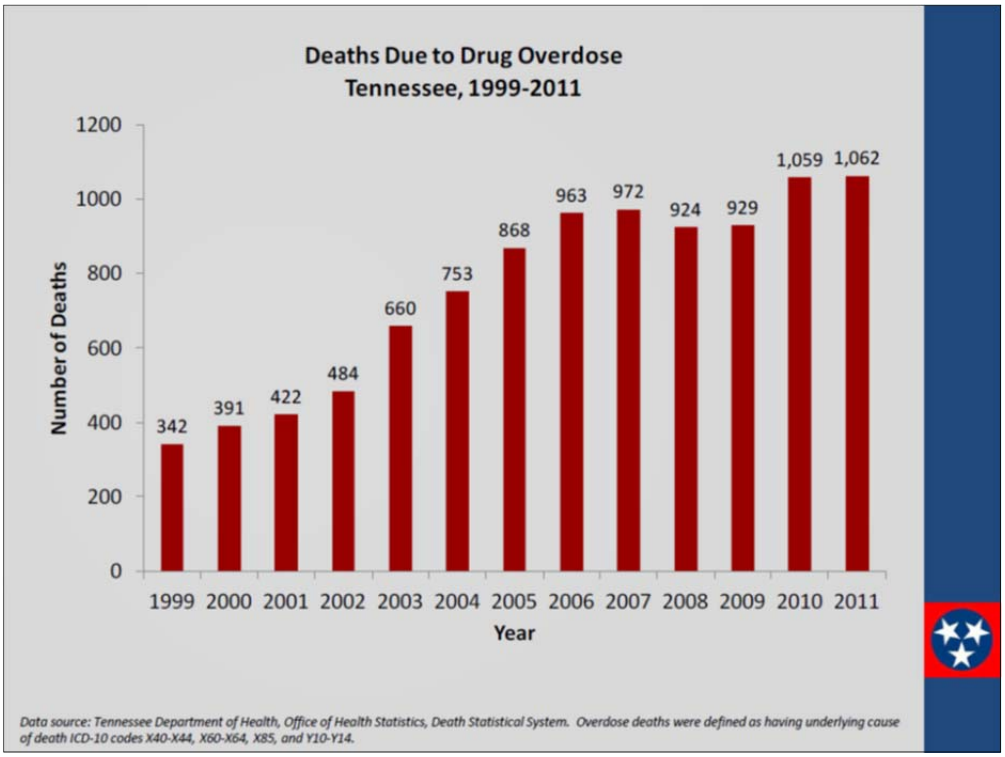
The implementing regulations of the ADA include drug addiction and alcoholism among the conditions constituting a physical or mental impairment. See 45 C.F.R. § 84 Appendix A, Subpart A.

[5] Citing *Bay Area Addiction Research and Treatment, Inc. v. City of Antioch*, No. C98-2651 (N. D. Cal. March 15, 2000); p. 10, n. 15. An individual has a record of a disability if he or she "has a history of ... a mental or physical impairment that substantially limits one or more major life activities." *Hilburn v. Murata Elec. North Amer., Inc.*, 181 F.3d 1220, 1229 (11th Cir.1999), quoting 29 C.F.R. § 1630.2(k)(1997). In this case, the Individual Plaintiffs and TCH provided evidence that the effects of having a drug addiction, and the lengthy treatment that it entails, impairs the major life activities of--at a minimum--working and parenting. Even if this court would decide that the effect of methadone treatment results in a mere transitory disability, Plaintiffs must still prevail on this issue because drug-addicted individuals can be shown to have a "record of" or are "regarded as" having a disability. See 42 U.S.C. § 12102(2)(B)and (C).

[6] *Rhj Med. Ctr. Inc. v. City of Dubois*, 754 F.Supp.2d 723 (W.D. Pa. 2010).

- Estimated costs of caring for these children increased from $29 million to over $52 million.
- In 2003, a CON was granted for the proposed area when the death rate was less than half its current rate, but it was ultimately stopped by Johnson City community leaders. Since then another 1,000 or so have died of drug overdoses in the proposed service area.

The death toll rate is on course to double in just a few year's time at present growth rates.

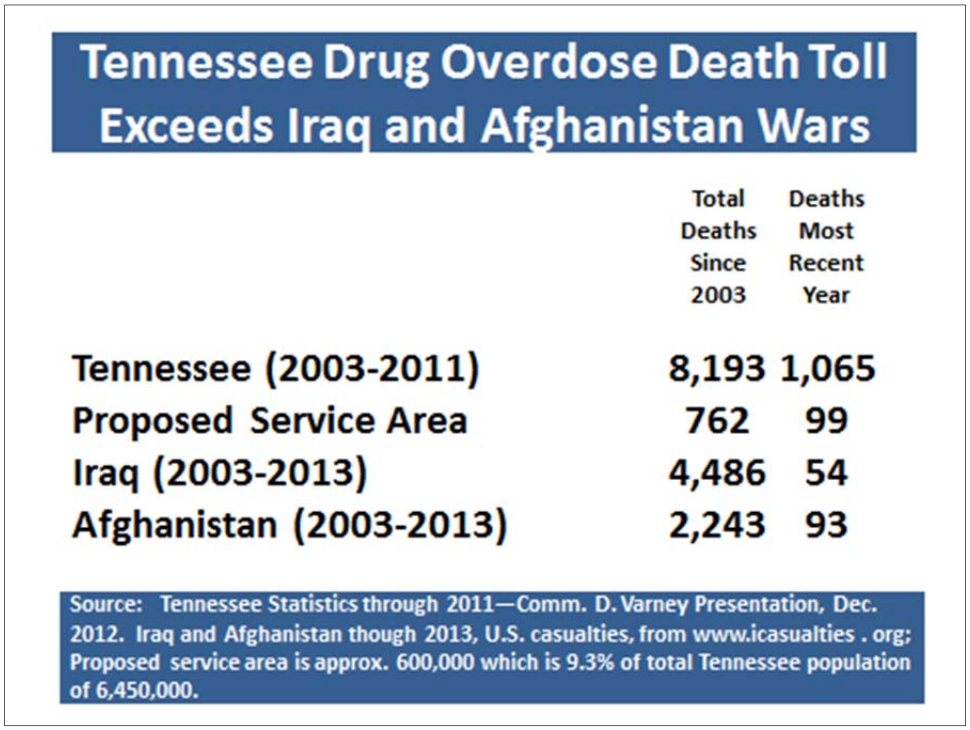


These death figures reveal a disaster both in the state as a whole and the proposed service area in particular.

- Even now, more than 1,000 die each year from drug overdose in Tennessee (1,062 in 2011).
- Death rate is more than doubling every ten years.
- Proposed service area population is 9.3% of the state population
- Approximately 100people in the proposed service area are projected to die from drug overdose each year into indefinite future (1 death every 2.9 days).

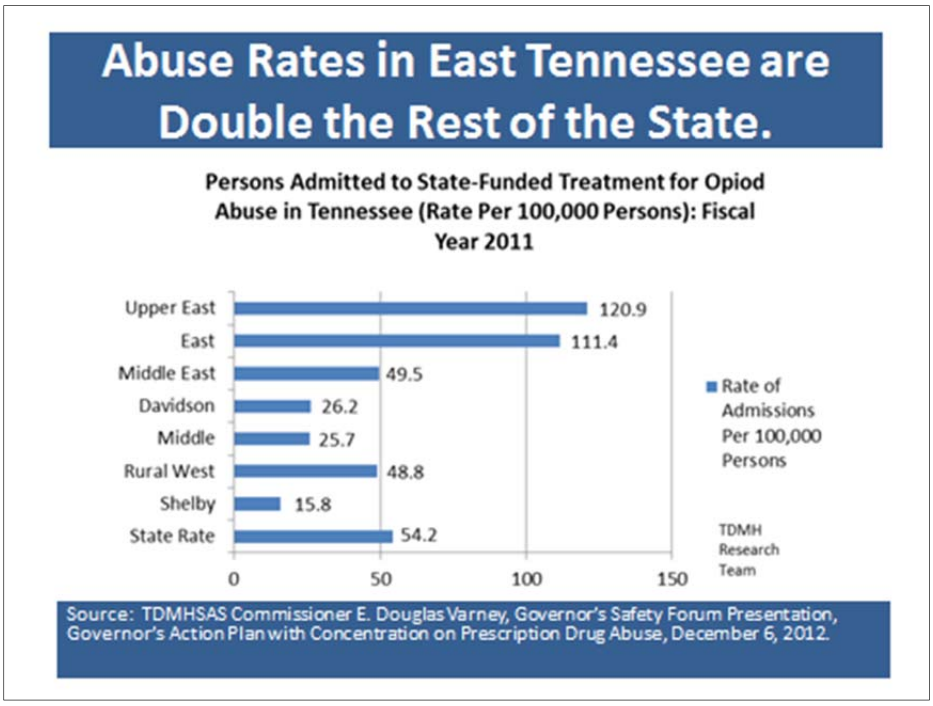
- Approximately 1,000 will die in the proposed service area from drug overdose over the next ten years.
- Assuming growth rate of drug overdose deaths continues, deaths in proposed service area will exceed 1,500 over ten years.

In fact, the opiate-addiction epidemic in Tennessee, and in East Tennessee in particular, is so bad that it's killing residents at a pace exceeding that of deaths of American service personnel in the Iraq and Afghanistan wars.

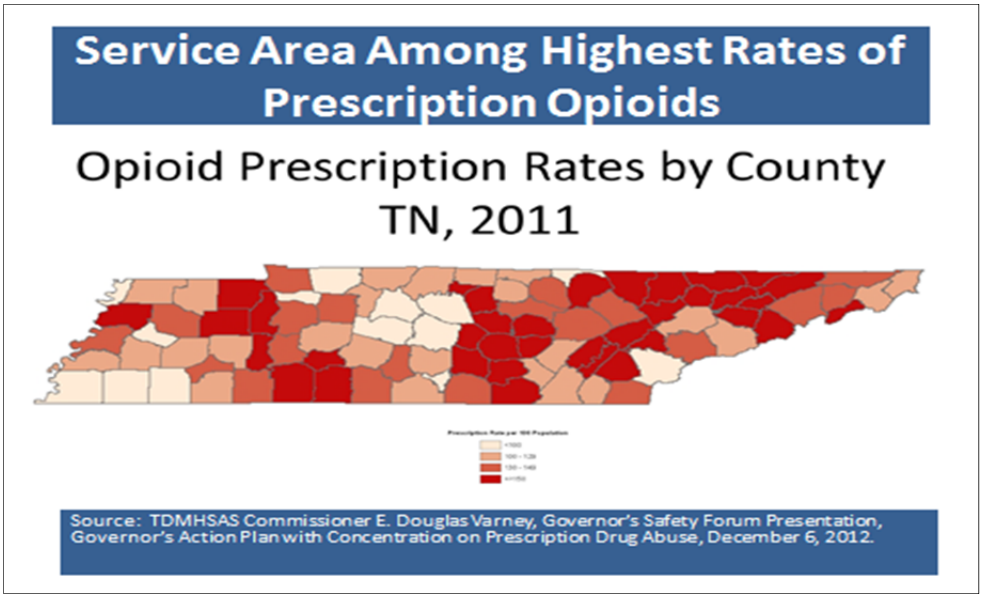


Presently, there appears no end in sight to these "war zone" levels of death from drug overdoses in Tennessee in general and East Tennessee in particular.

As presented at the CON hearing, from information provided by the Commissioner of the Department of Mental Health and Substance Abuse Services, the drug abuse problem in East Tennessee is more than twice as severe as the rest of the state



As presented at the CON hearing, some of the highest rates of prescription opioids in the state are in the proposed service area as shown below.



As presented at the CON hearing, it is an undisputed fact that for many, many patients, and certainly, without question, for opiate-addicted pregnant women, the

undisputed standard of care for the treatment of opiate addiction is MMT. The list of recognized United States and world health authorities that have determined that MMT is the standard of care in unmatched and unchallenged by any other medication for opiate addiction. Doctors in the United States, and around world, prescribe MMT for more than 1,000,000 patients every day to save their lives. Yet this standard of care treatment exists nowhere in the proposed service area to help combat this unfolding human catastrophe.

Specifically, they are the following organizations[7]:

NATIONAL INSTITUTE OF HEALTH (NIH)

NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

[7] National Institute of Health (NIH.gov); National Institute on Drug Abuse (NIDA.gov). 2; U.S. Substance Abuse & Mental Health Services Administration (SAMHSA.gov); Center for Disease Control (www.cdc.gov); The World Health Organization (WHO.org); The New England Journal of Medicine (JAMAnetwork.org); Journal of the American Medical Association (AMA-assn.org); American College of Obstetricians and Gynecologists (acog.org); HHS.gov.

U.S. SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)

AMERICAN SOCIETY OF ADDICTION MEDICINE

CENTER FOR DISEASE CONTROL (CDC)

WORLD HEALTH ORGANIZATION (WHO)

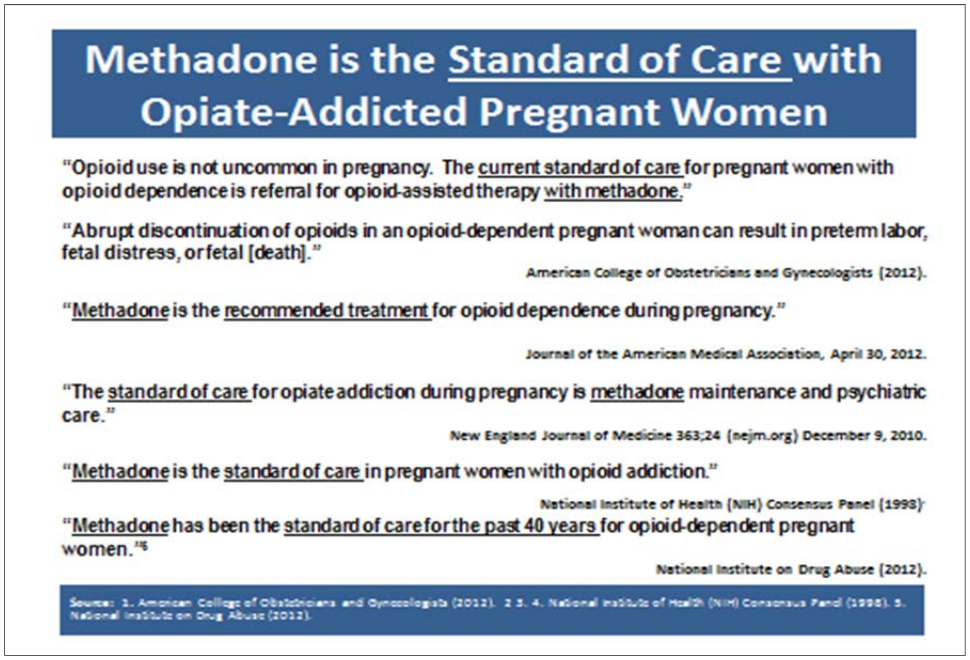
U.S. DEPARTMENT OF HEATH AND HUMAN SERVICES (HHS)

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

NEW ENGLAND JOURNAL OF MEDICINE

JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (AMA)

At the CON hearing, TCH presented the panel with the following additional authorities specifically holding that MMT is the unquestioned standard of care for opiate addicted pregnant women.



Specifically, the slide read as follows:

"Opioid use is not uncommon in pregnancy. The current standard of care for pregnant women with opioid dependence is referral for opioid-assisted therapy with methadone."

"Abrupt discontinuation of opioids in an opioid-dependent pregnant woman can result in preterm labor, fetal distress, or fetal [death]."

American College of Obstetricians and Gynecologists (2012).

"Methadone is the recommended treatment for opioid dependence during pregnancy."

Journal of the American Medical Association, April 30, 2012.

"The standard of care for opiate addiction during pregnancy is methadone maintenance and psychiatric care."

New England Journal of Medicine 363:24 (nejm.org) December 9, 2010.

"Methadone is the standard of care in pregnant women with opioid addiction."

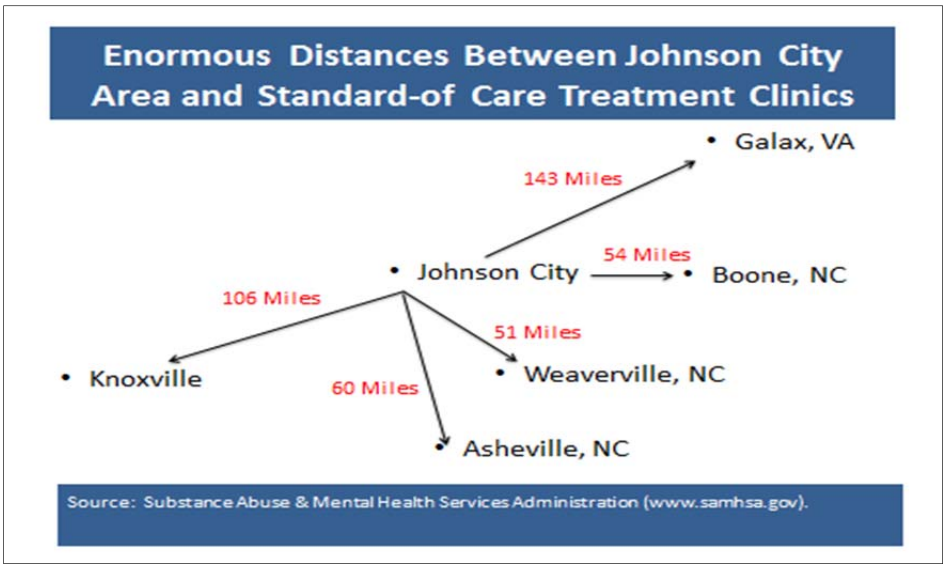
National Institute of Health (NIH) Consensus Panel (1998)

"Methadone has been the standard of care for the past 40 years for opioid dependent pregnant women."

National Institute on Drug Abuse (2012).

Undoubtedly, MMT is the long-accepted "standard of care" for opiated-addicted pregnant women because, among other reasons, it offers by far the highest treatment retention rate – and lowest relapse rate-- of any opiate addiction treatment. As such, methadone provides mothers with by far the lowest risk of fetal death due to relapse or withdrawal.

It was undisputed that all standard of care MMT clinics are more than 100 miles away roundtrip from large parts of the proposed service area.



Common sense holds that having to drive such enormous distances of more than 100 miles a day for 90 straight days or more is effectively a denial of access to treatment. Indeed, medical experts presented by TCH and Johnson City have agreed that making an opiate-addicted person drive 100 miles round trip to receive doctor prescribed, lifesaving treatment is equivalent to a denial of medical treatment. *Testimony of Dr. Robert Newman, May 24, 2013, at p.* 32; *Testimony of Dr. Stephen Loyd,* May 24, 2013, p. 30, l. 9-13.

My Individual Clients' drive must be made as often as daily to avoid serious withdrawal symptoms common to opiate-addicted persons: tremors; cramps; muscle and bone pain; chills; perspiration (sweating); tachycardia (rapid heartbeat); itching; Restless Legs Syndrome; flu-like symptoms; Rhinitis (runny, inflamed nose); yawning; sneezing; vomiting; Diarrhea; weakness; Akathisia (a profoundly uncomfortable feeling of inner restlessness).[8]

Standard of care MMT treatment is, tragically and without good reason, not available in the proposed service area. It was undisputed that the number of East Tennessee residents who have to endure this daily driving marathon of 100 miles or more to out-of-state MMT clinics is at least 400-500. North Carolina regulators refer to this daily mass movement of humans as a "migration." Spencer Clark, Director of the North Carolina Opioid Treatment Authority, confirmed the 400-500 daily "migration" and that the number "may be higher." This was all was presented without dispute at the CON hearing. This so-called "migration" occurs on mountain roads in all weather conditions and certainly includes instances of dangerous driving conditions during rain, sleet or snow.

[8] National Institute of Drug Abuse at the National Institute of Health (http://www.drugabuse.gov/drugs-abuse).

Subject: Approximate Total Patient Count of Tennessee Residents Being Served in NC OTPs in May, 2013
Date: 6/24/13 11:49:23 AM Slide 11
From: "Clark, Spencer"
To: "'kostertag@charter.net'"
Cc: "Bowman, Jennifer" , "Vanwy, Dolly" , "Worth, Smith" , "Davis, Brenda"

Kathy:

Our approximate total patient count of Tennessee residents being served in NC OTPs in May, 2013 is at least 400 unduplicated individuals.

The final figure may be higher than this as we have not yet received data from a survey of all of our programs.

Please do not hesitate to contact us if you have further questions.

Spencer Clark, Administrator
NC State Opioid Treatment Authority

Spencer Clark, MSW, ACSW
NC Department of Health and Human Services
Director of Operations and Clinical Services
Community Policy Management Section
Division of Mental Health, Developmental Disabilities and Substance Abuse Services
3007 Mail Service Center, Raleigh, NC 27699-3007
Telephone: (919) 733-4670 Fax: (919) 233-4556
Spencer.Clark@dhhs.nc.gov
http://www.ncdhhs.gov/mhddsas/

Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized State official. Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this email in error, please notify the sender immediately and delete all records of this email.

No virus found in this message.
Checked by AVG - www.avg.com
Version: 2013.0.3345 / Virus Database: 3199/6438 - Release Date: 06/24/13

TCH presented testimony at the CON hearing that this number is likely underreported and probably closer to 1,000 to 1,500. So at least 400-500 ADA-disabled persons--and possibly 1,000 to 1,500--are being forced, often as daily, as to drive enormous distances, more than 100 miles roundtrip for doctor-prescribed, life-saving, standard of care treatment that is available nowhere in the proposed service area. This fact was undisputed at the hearing.

Presently, my Individual Clients -- and at least between 400-500 Tennessee residents, and possibly up to 1,500 -- must drive more than 100 miles roundtrip each time they need to receive life-saving, doctor-prescribed, standard of care MMT treatment for their opiate addiction which is nowhere in the proposed service area.

Perhaps even more disturbing, is that new MMT patients, including pregnant women, are required to obtain medication in person at an MMT clinic for at least the

first 90 days straight with no ability to take home any medication, so this requires people in the proposed service area seeking treatment for first time to break their potentially deadly opiate addiction, including pregnant women, to drive up to 9,000 miles, or more, in the first 90 days of treatment to obtain doctor-prescribed, standard of care, life-saving medication.

TCH's proposed clinic in this area will be a life-saver to them in that it will reduce the enormous distances they must drive as often as daily –and the enormous toll such driving takes in the form of time and daily expense in gasoline, wear on their automobiles, exhaustion from having to wake up at 1-3AM to get in the car, with their children in car seats, and drive these enormous distances. All this driving consumes that time that could be devoted to family and work—all for treatment of a disability unquestionably recognized under the ADA and the RA. Tragically, too many of these poor people may well give up trying to get better in the face of these astronomical driving duties to stay in standard of care treatment and, instead, simply go back to much more convenient but illegal supplies of opiates such as pain pills and heroin — with inevitably horrible results and huge costs for them individually and for society as a whole.

In any other field of medicine, bringing standard of care treatment into a community is met with open arms. But for some reason—and these are factors within the inner depths of human character that are beyond my comprehension -- people sometimes allow themselves, or others, to suspend their sense of humanity when dealing with opiate-addicted people.[9] So standard of care treatment is effectively

---

[9] The U.N. Human Rights Council has even gone so far as to describe denial of opiate replacement therapy as "possibly torture:"

> "A particular form of ill-treatment and possibly torture of drug users is the denial of opiate substitution treatment, including as a way of eliciting criminal confessions through inducing painful withdrawal symptoms (A/HRC/10/44 and Corr.1, para. 57). The denial of methadone treatment in custodial settings has been declared to be a violation of the right to be free from torture and ill-treatment in certain circumstances (ibid., para. 71). Similar reasoning should apply to the non-custodial context, particularly in instances where Governments impose a complete ban on substitution treatment and harm reduction measures."

denied en masse to surely at least 400-500, and possibly well over 1,000, recovering opiate-addicted, ADA-disabled people.

The HSDA panel was clearly made aware of these facts, including, that a recovering opiate-addicted person, including pregnant women, must drive 100 miles per day for doctor-prescribed, standard-of-care, life-saving treatment during up to the first three months (90 days) of MMT treatment because it is nowhere available in the proposed service area. Obviously, this is a horrific, unnecessary burden on any person ---especially a disabled person and, even more, for pregnant disabled women— and is a clear violation of the ADA and RA.

During the CON hearing, the opponents of the CON application--led by officials of the Johnson City government, introduced evidence that the relatively new and untested methadone substitute – buprenorphine -- and its branded names Subutex and Suboxone, were somehow equivalent to MMT in safety and effectively. This is unquestionably false as these relatively risky, untested, and non-standard of care drugs are shown, at the very minimum, to be not as effective as methadone for avoiding potentially deadly relapses among patients. This is partly why more than 80% of OTP patients use methadone rather than less effective and non-standard of care medications. Opponents also attempted to show abstinence is an effective substitute to methadone, but with potentially deadly relapse rates running up to 90+% in abstinence therapy,[10] that contention does not withstand scientific scrutiny. It is undisputed that abstinence is definitely not the standard of care for pregnant women because it carries an extremely high chance of relapse and withdrawal which can result in fetal death.[11] Thus, and shockingly, the standard of care treatment to

---

See HRW, Lessons Not Learned: Human Rights Abuses and HIV/AIDS in the Russian Federation (2004). United Nations Human Rights Council, Twenty-second session, Agenda item 3, "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, Juan E. Méndez," A/HRC/22/53 (2013).

[10] "Lapse And Relapse Following Inpatient Treatment of Opiate Dependence" 2010, 103 (6):176-9 *Irish Med J.* (Follow-up interviews were conducted with 109 patients, of whom, 99 (91%) reported a relapse.). A US follow-up study of 10 000 opiate addicts (the Drug Abuse Reporting Program; Simpson & Friend, 1988) found 88% relapse rate for abstinence-based treatment. *Advances in Psychiatric Treatment* (2003), vol. 9, 280–288.

[11] American College of Obstetricians and Gynecologists (2012).

minimize risk of fetal death in an opiate-addicted pregnant women is unavailable in the proposed service area.

In fact, undisputed evidence at the CON hearing showed that Mountain States Health Alliance in Johnson City specifically warned doctors NOT to employ buprenorphine/Subutex/Suboxone with opiate-addicted pregnant women.

The warning was covered in the Johnson City Press on March 22, 2012 and read in part as follows:

> "If you are pregnant, trying to get pregnant or not using birth control, don't take Subutex or Suboxone, for the sake of your unborn child."
>
> * * *
>
> "And if you are a physician, don't continue to prescribe those drugs containing buprenorphine to anyone who is pregnant.
>
> * * *
>
> "Dr. Joy Anderson, a Mountain States Medical Group obstetrician and gynecologist practicing in Kingsport, said pregnant women are being told by physicians prescribing the two drugs 'it's a safe drug in pregnancy' when it is not

* * *

> "Methadone is the recommended medication used for detoxification during pregnancy, the MSHA literature says."

"Women Warned Not to Take Two Drugs Around Pregnancy", *Johnson City Press*, March 22, 2012. (http://www.johnsoncitypress.com/article/99175)(emphasis added).

It remains a mystery how Moutain States Health Alliance could oppose TCH's CON application in a letter to the panel and yet in 2012 warn local doctors that the methadone substitute buprenorphine/Subutex/Suboxone is dangerous to mothers and their unborn babies and that MMT is the standard of care treatment for opiate-addicted pregnant women as shown below.

At present, local opposition to the CON has resulted in my clients, and at least hundreds, and possibly well over 1,000 other disabled persons, to be forced into what amounts to a daily Bataan-like drive of thousands of miles to reach standard of care treatment in distant out-of-state clinics. Unbelievably, it's being forced upon them in area with an already out-of-control death rate for opiate addiction. It's a virtual certainty that forcing at least 400-500, and possibly up to 1,500, recovering addicts have to make these enormous daily drives result in some just giving up and going back to illegal opiates with much higher death rates.

REQUEST FOR REASONABLE MODIFICATION OR ACCOMMODATION UNDER THE ADA AND THE RA

My clients respectfully submit that TCH's application did satisfy the requirements of need, economic feasibility, and orderly development, and that it should have been approved. However, on June 26, 2013, it was denied. In doing so, the panel did not comply with my request for a reasonable accommodation to grant the Certificate of Need ("CON") under the AMA and the RA.

So the following facts were undisputed at the CON hearing:

- MMT is the standard of care for treatment of opiate addiction;
- MMT is the standard of care for opiate addicted pregnant women by offering the lowest risk of relapse, withdrawal, and fetal death, among other reasons;
- MMT is not available in the proposed service area and that it is at least 50 miles away by overland road to MMT clinics in North Carolina
- At least 400-500 (and evidence suggested this is number could be 1,000 to 1,500) East Tennessee residents drive to MMT clinics in North Carolina, as often as daily. This daily mass-movement of people is so large North Carolina regulators dubbed it a "migration."

- Commutes from many parts of the proposed service area to North Carolina MMT clinics presently exceed 100 miles roundtrip.
- Distance is a barrier to treatment. Tennessee Methadone Task Force found that "[g]enerally, the closer one lives to a treatment program, the greater likelihood of participation….The rate of participation is nearly twice as high for persons living in or close to one of the five counties that house programs, 59.0/100,000, than the rate for those that live 60 miles or more from a program, 32.2/100,000."
- Presently in the proposed service area, new MMT patients, including pregnant women, are required to drive 9,000 miles in the first 90 days of treatment for doctor-prescribed, life-saving, standard of care treatment.
- Without standard of care MMT, opiate-addicted mothers have a higher risk of relapse which is unquestionably associated with fetal death.
- So opiate-addicted pregnant women in the proposed in the proposed service area are now being forced to drive 9,000 miles for daily for unavailable standard of care treatment during the first 90 days at least, or elect to take more convenient, but less effective, non-standard of care medication that without doubt has a higher risk of relapse and withdrawal that can end up killing their baby.

Respectfully, we contend that, based on the above undisputed facts, my clients—and hundreds and, possibly well over 1,000 people like them—are effectively being denied access by HSDA to doctor-prescribed, life-saving standard of care MMT medication for their disability.

At a bare minimum, the clear and undisputed lack of life-saving standard of care treatment in the proposed service area should, per se, satisfy HSDA's criteria of need, economic feasibility, and orderly development, and certainly requires a reasonable modification if necessary to allow disabled reasonable access to treatment under the ADA and the RA.

Therefore, my clients have respectfully asked, and hereby respectfully ask again, that any and all alleged deficiencies in TCH's CON application be identified and that TCH be provided all reasonable accommodations or modifications to any and all applicable rules and requirements necessary to enable its application to be approved as required by the ADA and the RA. This will, in turn, enable my opiate-addicted clients, and hundreds of other disabled persons, to be afforded reasonable access to doctor-prescribed, life-saving standard of care MMT which would be the only such facility within 50 miles of Johnson City.

After the CON is granted, TCH will promptly apply to the Tennessee Department of Health for a license to operate its methadone clinic and it expects to promptly obtain zoning approval from Johnson City through federal court order if necessary under provisions of the ADA and the RA.

Once TCH has obtained the Certificate of Need from HSDA, along with a license from the Tennessee Department of Health, and zoning and other permit approvals from Johnson City, TCH is prepared to open its proposed OTP within a short time and provide my clients and hundreds of others access to life-saving, standard of care MMT for the first time.

Sincerely,
James A. Dunlap Jr. & Associates LLC

James A. Dunlap Jr.

JAD/jd